The regulatory status of the enzyme transglutaminase in the processing of raw and heated meat products in Germany
I. Introduction

Transglutaminase is an enzyme that is commonly found in nature (blood and liver of mammals, muscles of fish, micro-organisms) and also produced by microbial fermentation. It is used in the food industry for cross-linking of proteins in various processes.

The enzyme catalyzes acyl-transfer reactions between the gamma-carboxamide groups of protein bound glutamine and primary amines. If the epsilon-amino group of lysine acts as the primary amine epsilon-(gamma-Glu)Lys bonds are formed, which result in an intra- and intermolecular cross linking of proteins.

Depending on the food in question the addition of transglutaminase to the raw material followed by the food processing steps gives rise to the information of a framework of additional iso-peptide bonds which determines the functional properties of the food, for example such as gelation capability.

Transglutaminase is active within a wide pH range (pH 5-8). The enzyme is stable up to a temperature of 40 °C. Above 75 °C the enzyme looses its activity within a few minutes if used at usual dosages.

Transglutaminase is used to improve the texture an consistency of cooked meat products such as sausages and harms. Transglutaminase catalyzes the intermolecular linkage between glutamine and lysine residues in the proteins of the raw meat by raw meat by creating a complex network. At the end of the process the enzyme activity is destroyed by heat treatment.

There are numerous ways to reconstitute meat products, with one of them involving transglutaminase. Transglutaminase in raw meat provides an enzymatic way of creating uniform shapes and sizes due to the enzyme being able to catalyse the cross-linking between glutamine and lysine residues in liquefied proteins. Transglutaminase produces an effect on soluble proteins only changing their character in such a manner that a gel is produced. Those proteins are added to the food applications together with transglutaminase.
Transglutaminase does not enable cross-linking of meat proteins without the soluble phase (gel) being present, because the chance of relevant pairs of side-chains being available is virtually zero. The protein gels hold the reconstituted food together, while transglutaminase alone is not a part of the gel matrix.

The catalytic reaction of the enzyme with gelled proteins is always stopped by the depletion of substrate protein during processing. The enzyme may therefore be fond in its native form in the finished product, as it cannot be removed, but it is not functional due to lack of substrates.
II. Regulatory Status in Germany

The use of transglutaminase in foodstuffs is to be judged on the basis of the applying general rules (compare the statement of the German Federal Ministry of Food, Agriculture and Consumer Protection of 23 July 2008). There is no positive list in Germany regulating the use of food enzymes.

Transglutaminase is to be regarded as a processing aid, not as a food additive, although transglutaminase is added to a foodstuff due to technical reasons in the process of production or treatment, whereby transglutaminase itself or its brake down or reaction products become or can become a part of the foodstuff. Because there is no technological function in the final product, transglutaminase is legally to be assessed as a processing aid (§ 3 (3) LFGB).

In heated meat products like cooked ham transglutaminase does not exist any longer in the final product, because it is destroyed by the heating process. Thus, it has no longer any technological effect.

Using transglutaminase in the processing of raw meat or raw meat products, the enzyme does not have a technological effect in the final product as well. This is because the catalytic reaction of the enzyme with gelled proteins is stopped by the depletion of substrate protein during processing.

Different than food additives, processing aids do not need an authorisation. The only requirement is that processing aids do not present a risk for human health, which is not the case with respect to transglutaminase.

With regard to the declaration, there is no labelling required for final foods containing transglut. Processing aids are not categorized as a foodstuff ingredient and for this have not to be labelled in the ingredients list (§ 5 (2) LMKV).

Only with regard to the use in raw meat or raw meat products, a labelling could be necessary because of the general ban of misleading products or misleading product labelling (§ 11
LFGB). A misleading appearance could be assumed, when the final product would give the false impression that it does not consist of several pieces, but of a grown piece of meat.

However, the question of a possibly misleading appearance is eliminated by the law, which obliges to label the correct product name. Using the correct name of the product - for example “product XY assembled by pieces of meat” – avoids any misleading of the consumer with respect of the consistence of the product.

It results that there is no need to indicate transglutaminase in the labelling of the product, in order to avoid a possible misleading of the consumer, when the correct product name is indicated.